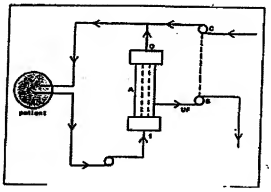
REMARKS

This Response is to the final Office Action mailed on May 13, 2009. Please charge Deposit Account No. 02-1818 for a One Month Extension of Time any other fees deemed owed. In the Office Action, Claims 1, 13 and 24 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 2 and 5 to 12 were rejected under § 103(a) as unpatentable in view of U.S. Pat. No. 6,254,567 to Dennis Treu et al. ("*Treu*") in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("*Roberts*"). Claims 3, 4 and 13 to 30, were also rejected under 35 U.S.C. § 103(a) as unpatentable in view of *Treu* and *Roberts*.

Claims 1, 13 and 24 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action states the phrase "consisting of" constitutes new matter in each of these claims, and that the Examiner cannot find support in the specification and drawings for the claimed fluid circuit. Claims 1, 13 and 24 have been amended to remove the "consisting of" language. Applicants respectfully submit that the amendments to the independent claims are not substantive in nature, although the amendments do broaden the claims. The amendments merely change the language back to its original form and should therefore be entered at this final rejection. Applicants submit that the § 112, first paragraph, rejection is therefore overcome.

Claims 1, 2 and 5 to 12 are rejected under § 103(a) as unpatentable in view of *Treu* and *Roberts*. Regarding Claim 1, Applicants respectfully request the Patent Office to review again the disclosure of *Roberts*, and in particular the finding that *Roberts* discloses using the drain flow rate to cause the dialysate to recirculate a plurality of times along the fluid loop (loop in communication with the patient). The Office Action's cited passage of *Roberts*, namely page 377, col. 1, second paragraph, discusses an alternative flow-through method that involves the use of fresh dialysate for inflow, while fluid in the patient's peritoneum is recirculated at a high flow rate. No value for the *high* flow rate is specified in the cited paragraph, but the paragraph immediately preceding the cited paragraph discusses recirculation rates of 100 ml/min or 200 ml/min. The cited paragraph does however indicate that an inflow flow rate (flow rate of fresh fluid into the recirculation loop) can be 30 ml/min. *Most importantly*, the passage says, "the outflow of the spent peritoneal dialysate would be adjusted to the inflow." Applicants submit that this statement means that the outflow is set to *match* the inflow. As evidence, Applicants

direct the Patent Office to Figure 7, reproduced below, of *Roberts* that shows a similar set-up to the one of the cited paragraph except that the recirculation loop of Figure 7 has a hemofilter.



Regarding Figure 7, page 374 of *Roberts* discloses that the recirculating rate is set at 200 ml/min. The inflow and outflow rates are *matched* or "adjusted" to be the same, i.e., to 36 ml/min. It should be appreciated that the spent dialysate outflow of both the cited passage at page 377 of *Roberts* and Figure 7 at page 374 of *Roberts* are analogous to the discharge fluid path of claim 1. It should also be appreciated that it is physically impossible to create a recirculation flow rate higher than the inflow rate by limiting the outflow rate. Thus, with the cited inflow rate of 30 ml/min at page 377, even if the outflow rate (discharge rate) was totally occluded to zero ml/min, the maximum valve the recirculation rate could achieve would be 30 ml/min. The only way to achieve the higher recirculation rates discussed in *Roberts* is to add a pump to the recirculation loop, which is precisely what is shown in Figure 7 by the pump circle located upstream of the hemofilter. Applicants accordingly respectfully submit that there is no cxpress teaching and no implied inferencc in *Roberts* to limit the outflow flow rate to create a recirculation rate as claimed in Claim 1. Instead, reading the cited language in context with *Roberts* as a whole, it is clear that *Roberts* contemplates a different flow regime detailed above, namely, to use a recirculation pump to achieve a higher recirculation flow rate.

Independent claims 13 and 24 include language similar to that of claim 1, namely, that the discharge rate is effective to cause the therapy fluid to be circulated a plurality of times in the fluid loop. The Office Action at Page 10 (for Claim 13) and Page 14 (for Claim 24) cites the

same passage of *Roberts* (col. 1, second paragraph on page 377) to teach those elements of Claims 13 and 24. As discussed above, there is absolutely no express or implied teaching in *Roberts* to use its outflow (discharge) rate to create recirculation, and instead the overall teachings of *Roberts* lead to a different conclusion, namely, that the inflow and outflow rates are matched and that a different means is used to create dialysate recirculation.

For the foregoing reasons, Applicants submit that the Claims 1, 13 and 24 are allowable at this time, rendering any additional rejections of their respective dependent claims moot, and that all claims are accordingly in condition for allowance. If the Examiner believes that a telephone conversation would expedite prosecution in this case, or would be of use in understanding the above distinction over *Roberts*, Examiner is respectfully requested to call the undersigned.

Respectfully submitted,

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